

Atty. Dkt. No. ABI1460-2
(071243-1301)

As discussed during the telephone interview, the present invention is directed to methods for administration of taxanes, formulations useful therefor, and articles containing same. Invention formulations are typically free of such potentially deleterious components as surfactants (see, for example, claim 66) and cremophor (see, for example, claim 67). Invention formulations can be frozen (see, for example, claim 48) or lyophilized (see, for example, claim 47) for storage, and remain stable for extended storage periods, even after reconstitution (see, for example, claim 49).

As a preliminary matter, since the present office action is responsive to Applicants' Request for Continued Examination filed April 8, 2002, it is respectfully submitted that this action should not have been made final. Moreover, several issues are asserted for the first time in this action, making the finality of this action clearly improper. Accordingly, withdrawal of the finality of the present action and reissuance of a non-final action setting forth any properly assertable grounds of rejection is respectfully requested.

In spite of the fact that the claims have been improperly and prematurely subjected to a final rejection, in efforts to be fully responsive, Applicants address herewith the issues raised in the final rejection.

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The rejection of claims 29-35, 46-51 and 66-85 under 35 U.S.C. 112, first paragraph, as allegedly not being supported by an adequate written description is respectfully traversed. Applicants respectfully disagree with the Examiner's assertion that the specification "does not state the use of 'taxanes' in the instant invention." (See lines 16-17 at page 2 of the Office Action). Contrary to the Examiner's assertion, express mention is made of taxane in Applicants' specification (see, for example, page 22, line 12 of Applicants' specification). Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claims 29-34, 46-51 and 66-93 under 35 U.S.C. 102(e) as allegedly being anticipated by Desai et al., U.S. Patent No. 5,916,596, is respectfully traversed. As discussed during the telephone interview, Desai and the present application

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are commonly owned, thus Desai is not the invention of another. To the extent there may be overlap between the claims of Desai and the present application, in the absence of a final rejection, Applicants will delete any potentially overlapping subject matter from the present claims so that a "same invention" double patenting issue is not applicable. Then, the only potential issue remaining would be a possible obviousness-type double patenting issue, which will be addressed below as part of the "103" discussion.

The rejection of claims 29-35, 46-51 and 66-93 under 35 U.S.C. 103(a) as allegedly being unpatentable over Desai et al., further in view of *Langer* (Seminars in Oncology 24: No. 4, Suppl 12, pp. S12-81 through S12-88 (1997)) is respectfully traversed. As acknowledged by the Examiner, Desai "does not teach dosage amounts and rates of administration." (See the last two lines at page 3 of the Office Action).

Further reliance on *Langer* is unable to cure the deficiencies of Desai. *Langer* does not disclose or suggest the methods of administration contemplated by independent claims 29, 31, 32 and 82; or the dry powder formulations contemplated by independent claims 46, 66 or 67; or the frozen formulation contemplated by independent claim 48; or the liquid formulation contemplated by independent claim 49; or the articles contemplated by independent claims 73 and 88. It is respectfully submitted that the combination of Desai and Langer can only be asserted as a result of hindsight; having benefit of the teachings of Applicants' disclosure, and such use of Applicants' specification is clearly improper.

In addition, as noted above, Desai and the present application are commonly owned, thus Desai is not the invention of another. Thus, to the extent the present claims are asserted to be obvious in view of Desai, an obviousness-type double patenting rejection could be asserted. If such an issue is raised by the Office, Applicants would consider submission of a terminal disclaimer to obviate such an issue.

In view of the above remarks, reconsideration and withdrawal of the finality of the present action, and issuance of a non-final action addressing any issues which may remain

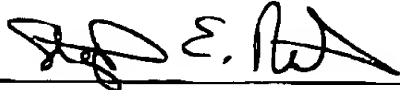
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in view of this communication are respectfully requested. In the event any such issues can be addressed telephonically, the Examiner is invited to call the undersigned at the number provided below so as to expedite further handling of this Application.

Respectfully submitted,

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